

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION)	MDL No. 1456
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339)	Civil Action No. 01-CV-12257 PBS
)	Judge Patti B. Saris

**AMGEN INC.’S REPLY IN SUPPORT OF ITS
MOTION TO DISMISS PLAINTIFFS’ CORRECTED
AMENDED MASTER CONSOLIDATED COMPLAINT**

Nothing plaintiffs argue in their opposition alters the conclusion that the “Corrected Amended Master Consolidated Complaint” (“CAMCC”) should, consistent with the Court’s prior orders in this case, be dismissed as to Amgen Inc. (“Amgen”). If anything, plaintiffs’ opposition reinforces the fact that, as to Amgen, the CAMCC still principally relies upon “guilt by association,” a theory which this Court has flatly rejected. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 307 F. Supp. 2d 196, 209-210 (D. Mass. 2004) (“AWP I”). What “new” Amgen-related “details” plaintiffs do allege are insufficient to infer fraud. Simply put, plaintiffs still have not plead sufficient *facts* to satisfy Rule 9(b). Accordingly, this Court should once again dismiss Amgen from the case.

Amgen agrees that the appropriate standard against which the CAMCC’s allegations against Amgen should be measured is the Court’s most recent decision in *AWP II*. The problem is that the CAMCC doesn’t measure up. In denying Amgen’s co-defendants’ motions to dismiss under Rule 9(b), the Court found compelling the fact that plaintiffs had described, for those defendants, “the factual investigations undertaken that formed the bases of plaintiffs’ allegations, and in so doing identify particular allegedly-fraudulent conduct on the part

of each Defendant....” *Id.* at 208. In particular, the Court cited plaintiffs’ reliance on government investigations, charts describing spreads calculated by the U.S. Department of Justice, and descriptions regarding the conduct of particular defendants by reference to specific “pricing mechanisms, government investigations, internal documents identifying spread, and related items.” *Id.* None of this exists to support plaintiffs’ allegations against Amgen.

Instead, plaintiffs continue to place faith in the unsupported and unsupportable notion that simply because Amgen operates in a competitive marketplace, its actions must, by definition, parallel those of its competitors. This is a theory that was first advanced in plaintiffs’ Amended Master Consolidated Complaint (“AMCC”), and swiftly rejected by this Court. *Compare* AMCC ¶ 221 *with* CAMCC ¶ 225A. Clearly, without more, competition does not equal fraud. Unable to come up with that “something more” for Amgen, plaintiffs instead point to allegations that *Immunex* marketed the spread or the apparent surmise of *another* company – facts on which plaintiffs also relied in unsuccessfully opposing Amgen’s prior motion – as somehow confirming *Amgen’s* participation in promoting an alleged spread. *See* CAMCC ¶¶ 225A, 225B. What plaintiffs ignore is that what *Immunex* allegedly did, and what *Centocor* allegedly may have thought, cannot be used to attribute fraudulent conduct to Amgen.

Plaintiffs’ other allegations similarly attempt to impute to Amgen allegedly fraudulent conduct by other defendants. For example, Amgen points out in its motion that plaintiffs’ allegation that Amgen purportedly marketed the spread in connection with the sale of *Aranesp*[®], rests on conduct by *Ortho*, not Amgen. *See* Amgen’s Mot. to Dismiss at 5-6. Plaintiffs do not dispute this point. Instead, they simply reiterate the CAMCC’s bald allegation that Amgen sales representatives “either handed out calculations showing the spread off of AWP that could be made or orally described that spread to physicians.” Pls.’ Opp. at 4. No physician

who supposedly received such a calculation is identified. No Amgen sales representative who supposedly provided such a calculation is named. Plaintiffs are unable to offer even a single instance of when or where such statements supposedly were made. Unlike similar allegations asserted against other defendants, plaintiffs can point to no document, no investigation, no advertising circular or other factual basis that might even begin to serve as some support for such an allegation. They just say it. While this may be adequate for purposes of pleading under Rule 8, it certainly does not meet the standard under Rule 9(b).

Plaintiffs also assert that they have alleged “specific fraudulent spreads” for Amgen products. They have not. Plaintiffs have merely taken the published AWP for a single Amgen product, Neupogen[®] (information that is publicly available through the compendia or on Amgen’s website), and simply compared that number to their own “real” AWP, a number that is neither defined nor explained. To this extent, the CAMCC fails to state a claim against Amgen for the same reasons the *Suffolk County* complaint, a related litigation before this Court, must also fail. In both actions, the resulting “specific fraudulent spread” on which plaintiffs rely is nothing more than pure conjecture. Again, unlike allegations against other defendants, the so-called spread is not supported by any government audit or investigation, by reference to any internal document, or anchored to any similar allegation of fact. *See* Amgen Mot. to Dismiss at 7-8. Rather than address this point, plaintiffs choose simply to ignore it, and offer no explanation as to how they calculated any “specific fraudulent spread.” Rule 9(b) and this Court require plaintiffs to provide clear and concise allegations of fraudulent AWP. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003); *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232 (1st Cir. 2004). Plaintiffs’ simple say-so does not satisfy their pleading obligation.

Finally, plaintiffs' opposition summarily claims that discounts render a company's AWP "inflated and phony." Pls.' Opp. at 4 & 6. Plaintiffs claim that because Amgen provides a discount on Aranesp[®], its reported AWP, which is posted on the company's website, must be "phony."¹ *Id.* at 4. This argument is fundamentally flawed. First, Congress has made clear that discounts, when properly reported, are lawful. *See* 42 U.S.C. §1320a-7(b)(3)(A); 42 C.F.R. § 1001.952(h). Plaintiffs do not dispute this point. Second, plaintiffs have not shown how the (lawful) provision of discounts to customers is tied to the allegedly unlawful manipulation of AWP, let alone any effort to market the "spread." Accordingly, these claims cannot support an inference of fraud.

In any event, plaintiffs wholly fail to explain how pricing decisions made after the filing of the complaint in this case can conceivably serve to support an inference of fraud. Plaintiffs' theory is that Amgen was posting "phony" or fraudulent AWP's for its products, and that plaintiffs relied on the AWP's to their detriment. As a matter of both fact and law, plaintiffs were thus keenly aware of the alleged fraudulent scheme and could not have been misled by, or justifiably relied on, an AWP that Amgen posted months after the complaint was filed in this case. *See* Amgen Mot. to Dismiss at 3-4.

In sum, plaintiffs have not cited to any governmental investigation of Amgen (in fact, the opposition concedes that Amgen has not been investigated by the government); have not provided any example, based upon internal company documents or otherwise, of Amgen's supposed manipulation of its products' AWP or of any marketing of the so-called "spread"; have not identified any misleading or fraudulent communication between Amgen and the compendia;

¹ Plaintiffs' allegations relating to the content of Amgen's website are also nothing new. Indeed, the content of Amgen's website was before this Court in connection with Amgen's Motion for Reconsideration. *See* Amgen's Corrected Mot. for Reconsideration, filed Mar. 8, 2004, at 2 & n.2. More to the point, the website merely recites information that is publicly available regarding the reported average wholesale price.

and have not identified even a single example of Amgen providing unlawful inducements to physicians or any other example of allegedly unlawful conduct in connection with marketing its products. Accordingly, no adequate basis exists to keep Amgen in this case.

Conclusion

For the reasons set forth above and in Amgen's initial memorandum in support of its motion to dismiss, Amgen respectfully requests that as to it, the Corrected Amended Master Consolidated Complaint be dismissed with prejudice.

Respectfully submitted,

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Dated: August 31, 2004

CERTIFICATE OF SERVICE

I hereby certify that on this 31st day of August, 2004, a true and correct copy of Defendant Amgen Inc.'s Reply In Support Of Its Motion To Dismiss Plaintiffs' "Corrected Amended Master Consolidated Complaint" was served upon all counsel of record via electronic service pursuant to CMO No. 2 by causing a copy to be sent to Verilaw Technologies for posting and notification.

/s/ Douglas S. Brooks
Douglas S. Brooks